

## B. REMARKS

A first Patent Office Action sent on March 1, 2005 was received. The Office Action was responsive to only claims 1-8 and 24 due to a restriction requirement, and claims 9-23 and 25-27 were withdrawn from further consideration. Enclosed herewith is applicants' response to said Office Action. Amended claims 1-6 and 24 are presented, along with new claims 28-30. Claims 4 and 7 are cancelled.

The claims have been amended in an attempt to overcome the rejection under 35 USC § 103 (a) 35 USC§ 102 (a) with regard to US patent 6,086,856 to Saferstein et al. Applicants' invention is for topical, not oral use as '856. Although the composition of '856 is meant to be expectorated, there are certain non-ingestible ingredients that would not be part of a formulation that could accidentally be swallowed (see 6,086,856 column 12, lines 18-20). As is the case with many dentifrice compounds, sometimes the formulations are accidentally swallowed. The compositions of the instant invention are topical, and the addition of non-ingestible ingredients insure that there is no possibility of accidental swallowing them since they are topically applied to skin and not applied orally.

Along these lines, claim 1 has been added to include at least one non-ingestible skin protectant, and claim 6 has been amended to include only topical skin protectants of aluminum hydroxide gel, calamine, kaolin, petrolatum, lanolin, talc and topical starch. Applicants are confident that these amended claims, which particularly point out and distinctly claim their invention, will now satisfy Examiner's concerns. Claim 1 has also been modified to include a minimum of about 0.05% to 1% of a stabilizer. This change negates the problem of 'zero' being included in the claimed range of stabilizer present in the formulation, thereby negating its presence. Claim 8, relating to the peroxide foam's reversibly compressible and decompressible container housing which operates at atmospheric pressure is included and has not been amended. Since it is dependent on amended claim 1, it is now deemed to be allowable.

Further amendment to claim 1 includes the addition of at least one topical pain reliever. The non-ingestible skin protectant and topical pain relievers are no longer optional ingredients, but are included in claim 1. This insures that applicants' invention is totally distinct from Saferstein or other dental use of hydrogen peroxide.

Examiner has pointed out Saferstein's use of topical pain relievers and skin protectants on page 4 of the Office Action as "menthol, glycerol, or propylene glycol". In column 7, lines 56 of '856, menthol et al are listed as demulcents. "Demulcents" are not pain relievers, but are compounds which contain soothing substances which become slippery when it contact with moisture. Common uses for demulcents are to reduce irritation of the digestive system, ease coughing due to bronchial tension, and to relax spasms in the bladder and urinary system. These uses are achieved by digestion of the demulcent, and not topical use. A US patent (6,703,039) to Xia et al and assigned to Bausch & Lomb uses demulcents to relieve "dry eye". In the latter case, the demulcent is not used topically on skin and is not ingested, but is used to protect and lubricate surfaces of the eye column 1 lines 15-20. Relevant pages of '039 and other information on demulcents are included in the appendix of the present communication.

In the attached appendix the first five pages are information found on demulcents, including the first two pages of US patent 6,703,039 with the appropriate sections marked. The next three pages from several web sites (gpnotebook.co.uk and healthy.net/scr) with additional information on demulcents.

Saferstein's use is not delineated but is called "auxiliary components". In any case, Applicants' claimed pain relievers are NOT demulcents. The identity and use of the topical pain relievers of Applicants' invention are separate and distinct from those of the cited prior art. The pain relievers claimed in the present invention are well-known but have heretofore not been formulated with a stable hydrogen peroxide foam product. As stated in amended claim 5, they include benzocaine, butamben picrate, dibucaine hydrochloride, dimethisoquin

hydrochloride, dyclonine hydrochloride, lidocaine, lidocaine hydrochloride, pramoxine hydrochloride, tetracaine, tetracaine hydrochloride, benzyl alcohol, camphor, camphorated metacresol, juniper, phenol, phenolate sodium, resorcinol, diphenhydramine hydrochloride, tripelenamine hydrochloride, hydrocortisone, hydrocortisone acetate, methyl salicylate, methyl nicotinate, capsaicin, capsaicin oleoresin.

Menthol, which was originally part of the Markush group of claim 5, has been omitted. It is also not included in new claim 29. Glycerin, which is identical to glycerol, has been deleted from claim 6 as well to avoid any §102 issues.

As was stated above the peroxide compositions of the Saferstein invention are meant to be a "non-ingestible expectoratable" formulation (see 6,086,856 column 12, lines 18-20). As with many dentifrice compounds, sometimes the formulations are accidentally swallowed. The compositions of the instant invention are topical, and there is no possibility of accidental swallowing them since they are topically applied to skin.

This is an important point of differentiation between applicants' hydrogen peroxide foam and Saferstein's invention. Applicants' invention, with currently amended claim 1, includes petrolatum, calamine, and dimethicone among the pain relievers of amended claims 1, 5, and 29. Not only are these not used by Saferstein, they are unable to safely be incorporated in a hydrogen peroxide composition that could be used in the mouth and accidentally swallowed.

The aforementioned appendix has pages six through eighteen concerned with the various and largely unknown dangers of the skin protectants used in the present invention. Those concerned with petrolatum begin on page six of the appendix and are highlighted here as follows:

#### **News Flash**

"Petrolatum – Impurities in Petroleum Jelly or commonly known as Vaseline, under suspicion in Breast Cancer – Petrolatum Banned in products in the EU – Long term damage to health becoming evident-..."

On the next page of the "News Flash" the following quote is directly relevant to the amendments and remarks of the present response:

"But the agency allows any amount of petrolatum of any purity in personal care products, many of which are applied directly to the lips and swallowed. Manufacturers would find no legal impediments to using the same unregulated petrolatum in personal care products as can be used in shoe polish."

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The appendix continues with references to petrolatum until page eleven. The information of the toxic effects of calamine and dimethicone are on pages twelve through eighteen.

10 As can be seen by a brief review of the citations, the ingredients of the topical pain relievers and skin protectants of the current invention are patently distinct from the formulation of Saferstein. They also could not be safely formulated in any non-topical hydrogen peroxide solution.

15 In summary, Applicants have amended claim 1 to avoid the cited prior art. Claims 2 and 3 are amended to include the term 'peroxide' in their preambles, and not substantively changed as they depend on Claim 1 which has been amended. Claims 5 and 6 have been amended; Claim 5 is now dependent on claim 1, and claim 6 has an amended preamble and now includes ONLY non-ingestible skin protectants.

20 Claims 4 and 7 have been cancelled. Claim 8 is as was filed originally. Claim 24 has been amended to include only non-ingestible topical skin protectants, and new claims 28 and 29 depend on amended claim 24 and specifically list the pain relievers and skin protectants that are part of Applicants' invention. New claim 30 indicates that the shelf life of the hydrogen peroxide foam is about two years.

25 It is felt that the amended, new and canceled claims now particularly point out and distinctly claim the instant invention, without infringing the prior art. Applicants are grateful for Examiner's corrections and comments and trust that this response to Office Action puts the application in condition for allowance.

30 Since claims 9-23 and 25-27 have been cancelled, no fee is due for the three new dependent claims presented herein.

Examiner is encouraged to speak with their representative if there are any questions.

Respectfully submitted,  
R.L. Smith et al

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**CERTIFICATE OF MAILING**

I hereby certify that this correspondence, and attachments, if any, will be deposited with the United States Postal Service by First Class Mail, postage prepaid, in an envelope addressed to MS Non-Fee amendment, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.

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Date of Signature 5-16-05

The commissioner is hereby authorized to charge payment of any fees associated with this communication to Deposit Account No. 500224

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By  Date 5-16-05  
Lori M. Friedman